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#17  
B. Webb  
12/9/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Michael R. Rosen, et al.

U.S. Serial No.: 09/505,458

Examiner: F. Oropeza

Filed : February 11, 2000

Group Art Unit: 3762

For : CARDIAC REMODELING

1185 Avenue of the Americas  
New York, New York 10036  
November 27, 2002

Assistant Commissioner of Patents  
Washington, D.C. 20231

**RECEIVED**

**DEC - 6 2002**

Sir:

TECHNOLOGY CENTER R3700

COMMUNICATION IN RESPONSE TO AUGUST 28, 2002 OFFICE ACTION

This Communication is submitted in response to the August 28, 2002 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the August 28, 2002 Office Action is due November 28, 2002. Accordingly, this Communication is being timely filed.

Reconsideration and allowance in view of the comments which follow are respectfully requested.

Claims 1-60 are pending, including independent method claims 1, 20 and 39 and independent apparatus claims 12, 31 and 50.

In the Office Action dated August 28, 2002, the Examiner stated that in applicant's Amendment dated May 22, 2002, claims 5, 9, 10, 12, 21, 24, 31, 34, 40, 43, 47, 48 and 50

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were successfully amended to address the 35 U.S.C. 101 rejections and 35 U.S.C. 112 rejections of record, and that the objections to the specification and claim 50 were also successfully amended.

The Examiner stated that Applicant's arguments with respect to claims 1-60 have been considered but are moot in view of the new ground(s) of rejection.

In the August 28, 2002 Office Action, the Examiner stated that the listing of references in the specification is not a proper information disclosure statement, and that 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." The Examiner stated that unless the references have been cited by the examiner on form PTO-892, they have not been considered. Applicant acknowledges this.

The Examiner rejected claims 1, 9-11, 20, 28-30, 39 and 47-49 are rejected under 35 U.S.C. 102(e) as being allegedly anticipated by Ben-Haim et al. (US 6363279). The Examiner stated that Ben-Haim et al. teach a method of modifying the force of contraction of a heart by applying a non-excitatory electrical field. The Examiner stated that the mechanical activation of the heart is controlled by electrical stimulation where action potentials from the S-A node enter the heart conduction system and propagate through the ventricles of the heart by sequentially activating connected muscle fibers (citing c 1, 11 31-45). The Examiner stated

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that this invention focuses on controlling the heart by modifying the action potentials, the ionic pumps and the channels of the heart (citing c 2, 16- c 3, 1 32).

The Examiner stated that this invention focuses on controlling the heart by modifying the channels that connect the heart; the channels are read to include gap junction channels (citing c 2, 16 - c 3, 1 32). The Examiner stated that according the Ben-Haim et al., these channels of the heart are modified by electrical stimulation (citing c 27, 11 12-27; c 27, 11 52-57; c 31, 11 1-5). The Examiner stated that Ben-Haim addresses the controlling the channels of the heart. The Examiner stated that the gap junctions channels are not specifically mentioned, but that it is inherent that the Ben-Haim et al. invention controls the gap junction channels as they are an essential component of the heart conduction system as noted in the art made of record (citing Winslow et al. US 5947899, c5, 1 28 - c 6, 1 3 and c 6, 11 33-53).

The Examiner stated that refractory periods are modified by electrical stimulation (citing c 8, 11 3-5; c 8, 1 66 - c 9, 1 3; c 9, 11 15-19; c 17, 11 26-35; c 17, 11 26-31; c 47, 11 37-45).

The Examiner stated that ion channels are modified by electrical stimulation (citing c26, 1 62 - c 27, 1 27; c 27, 11 43-57; c 31, 11 1-5).

The Examiner stated that changes in the heart occur over time as the heart is remodeled (citing c 9, 11 51-55; c 38, 1 48 - c 39, 1 10). The Examiner stated that electrodes can be attached by sewing (citing c 30, 11 9-12). The Examiner

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stated that electrodes can be placed in the heart or in vessels (citing c 37, 11 30-35 and c 40, 11 48-51). The Examiner stated that Electrodes can be activated in pairs (citing c 37, 11 15-17).

The Examiner rejected claims 2, 5, 2, 13, 15, 21, 24, 31, 32, 34, 40, 43, 50, 51, 53 and 58-60 as being allegedly obvious unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (US 5681308).

The Examiner stated that as discussed above, Ben Haim et al. disclose the claimed invention except for the 7cm x 1 cm (claims 4, 23 and 42) strip (claim 2, 13, 21, 32, 40 and 51) of electrode material having linked multiple electrode pairs, where the pairs are arranged in two columns (claims 12, 31 and 50) with one electrode in each pair in one column and the other electrode in each pair in the other column (claims 5, 15, 24, 34, 43, 53, and 58-60).

The Examiner stated that Edwards et al. disclose an analogous mapping apparatus and teach that it is known to use a circuit (38) mounted on a membrane support (16) to serve as a cardiac electrode which provides columns of individually controlled treatment electrodes (34) which can be multiplexed to enable stimulation of electrode pairs (citing figure 7 and c 7, 1 38-52).

The Examiner stated that absent any teaching of criticality or unexpected results, it is understood the electrode can be configured as a 7cm x 1 cm strip with only two columns of electrodes. The Examiner stated that the configuration change is an obvious change in shape based on the specific

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application. The Examiner stated that therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the electrode as taught by Edwards et al. to provide a flat electrode with multiple electrode measurement and stimulation configurations so the cardiac tissue can be more effectively treated.

The Examiner rejected claims 3, 4, 14, 17-19, 22, 23, 33, 36-38, 41, 42, 52 and 55-57 as being allegedly obvious over Ben-Haim et al. (US 6363279) and Edwards et al. (5681308) in view of Dahl et al. (US 5203348).

The Examiner stated that as discussed above modified Ben-Haim et al. disclose the claimed invention except for:

- the electrode strip of polyurethane (claims 3, 14, 22, 33, 41, and 52),
- the electrode comprised of platinum or consisting essentially of unalloyed platinum (claim 17-18, 36-37 and 55-56), and
- the electrode connected to insulated stainless steel wire (claims 19, 38 and 57).

The Examiner stated that Dahl et al. disclose an electrode and teaches that it is known to fabricate an electrode with a platinum or platinum alloy conductor or conductor with a stainless steel core (citing c 5, 11 19-36), and a lead with a medical grade polyurethane sheath and a stainless steel coated conductor (citing c 5, 11 23-38). The Examiner stated that, therefore it would have been obvious to one having ordinary

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skill in the art at the time the invention was made to modify the modified method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the materials of construction as taught by Dahl et al.. The Examiner stated that one having ordinary skill in the art would have been motivated to make such a modification in electrode to specify materials of construction that have proven electrical properties.

The Examiner rejected claims 7, 8, 26, 27, 45 and 46 as being allegedly obvious over Ben-Haim et al. (US 6363279) in view of Dahl et al. (US 5203348).

The Examiner stated that as discussed above, Ben-Haim et al. disclose the claimed invention except for the electrode comprised of platinum or consisting essentially of unalloyed platinum.

The Examiner stated that Dahl et al. disclose an electrode and teaches that it is known to fabricate an electrode with a platinum or platinum alloy conductor (citing c 5, 11 23-38).

The Examiner stated that therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the platinum of platinum alloy conductor as taught by Dahl et al..

The Examiner stated that one having ordinary skill in the art would have been motivated to make such a modification in electrode to specify material of construction that have proven electrical properties.

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The Examiner rejected claim 6, 16, 25, 35, 44 and 54 as being allegedly obvious over Ben-Haim et al. (US 6363279) and Edwards et al. (US 5681308) in view of Ideker (US 5873896).

The Examiner stated that as discussed above, modified Ben-Haim et al. disclose the claimed invention except for the electrode pair being 2mm from each other and the electrode pairs being spaced at least 5mm apart.

The Examiner stated that Ideker teaches a cardiac device for reducing arrhythmias and teaches that it is known to use an electrode configuration of an elongate primary strip with a plurality of electrodes positioned at spaced intervals, e.g. 1-4 millimeters (c 3, 11 2-4). The Examiner stated that, therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the electrode spacing as taught by Ideker to provide electrode spacing known to effectively reduce cardiac arrhythmias.

Applicant will address the rejections based on the Ben-Haim et al. U.S. Patent No. 6,363,279 particularly those rejections of anticipation of independent method claims 1, 20 and 39. The Ben-Haim reference relates to a device which applies an electrical field to the heart. Ben-Haim et al. state that their device modified the plateau currents, resulting what is claimed to be an increase in force of contraction. However, this reference does not contain any teaching or disclosure, explicitly or inherently, for causing the heart to be excited

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and activated, resulting in remodeling gap junctions, inducing ion channel remodeling or altering the effective refractory period.

The presently claimed invention of claims 1, 20 and 39 provides an electrical stimulus to the heart that excites the heart and results in altered activation, which must occur for the downstream changes to occur in remodeling gap junction, inducing ion channel remodeling or altering the effective refractory period. While the objective of the Ben-Haim et al. device is to improve cardiac failure, the methods of the presently claimed invention are to prevent or reverse arrhythmias of many causes (by remodeling gap junctions, inducing ion channel remodeling or altering the effective refractory period), not just causes associated with congestive failure. For the foregoing reasons, applicant urges that Ben-Haim et al. fail to disclose, explicitly or inherently, the methods of claims 1, 20 and 39.

The other rejections are based on the Ben-Haim et al. reference in combination with at least one other reference, and rely on the Ben-Haim et al. reference as a primary reference. However, as discussed above, the Ben-Haim et al. reference fails to teach or suggest any aspect of remodeling gap junctions, altering the refractory period in the heart, or inducing ion channel remodeling. The other references also fail to remedy the deficiencies of Ben-Haim in this respect. Therefore, these proposed combinations necessarily fail to teach or suggest the claims against which they were cited. Moreover, applicant urges that there is no teaching or suggestion in the prior art or otherwise of anything that would motivate one of ordinary skill in the art to combine the references as proposed by the Examiner.



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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invites the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.



Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner for Patents,  
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